

Valve-occlusion balloon 206 can be formed in various ways. For example, it can be formed using a material that is more compliant than that from which occlusion balloon 204 is formed. Alternatively, both balloons may be manufactured of the same material, however valve-occlusion balloon 206 may be formed with a wall thickness that is less than that of occlusion balloon 204 to thereby render it more flexible. If the balloons are independently inflatable, valve-occlusion balloon 206 may be created by inflation to a lower pressure than that used to inflate occlusion balloon 204. A check valve or the like may be used to achieve underinflation of one balloon relative to the other. Alternatively still, valve-occlusion balloon 206 can have a shape that allows an increase in pressure in the treatment space between the balloons to facilitate removal of fluid from the treatment space past the valve-occlusion balloon. For example, valve-occlusion balloon 206 may be of a different shape and/or size relative to occlusion balloon 204 so that the area of contact between valve-occlusion balloon 206 and the interior wall of vessel 201 is smaller than the area of contact between balloon 204 and the interior wall of the vessel 201.

By eliminating the need for a separate drain lumen, the valve-occlusion balloon allows a catheter shaft of the same outer diameter to have a larger central, injection or guidewire lumen, or smaller catheter shaft, than would otherwise be possible. Likewise, if the device is intended to allow blood perfusion during the treatment procedure, the central lumen can be used for blood flow, thereby allowing a higher rate of flow through the catheter than would be possible if a separate drain lumen were required.

Infusion of a flushing fluid into a treatment space defined by two occluding balloons, as described above with reference to FIGS. 12A and 12B, following introduction of the photoinitiator or prepolymer may, in some circumstances, fail to completely flush the treatment space. With reference to FIG. 13A, this may result in unwanted residual material at the proximal end 203 of the treatment space adjacent proximal occlusion balloon 204. This effect can be eliminated by providing a baffle 252 on the catheter shaft 202 to direct fluid injected into the treatment space toward the proximal occlusion balloon 204 to thereby provide sufficient mixing and flushing at the proximal end of the treatment space. In this embodiment, baffle 252 comprises an elastic sheath 254 which surrounds the catheter shaft 202 in the region of an injection port 208 and is secured to the catheter shaft by an adhesive 256 at a location distal to the injection port 208. As is shown in FIG. 13B, fluid 210 exiting the injection port expands the elastic sheath 254 and is caused to flow proximally in the treatment space toward the proximal occlusion balloon 204. The proximal fluid flow removes residual material positioned at the proximal end 203 of the treatment space adjacent to the proximal occlusion balloon. Upon reaching the proximal end of the treatment space, the fluid begins a distal flow through the entire treatment space and ultimately flows beyond a distally-positioned valve-occlusion balloon 206. Fluid exiting from the injection port 208 is prevented from flowing immediately in the distal direction by the adhesive 256 which is used to secure the elastic sheath 254 to the shaft, effectively creating a barrier. Upon completion of the fluid injection, the elastic sheath 254 retracts about the injection port 208 and catheter shaft 202 into the configuration shown in FIG. 13A to prevent fluid in the treatment space from retrograde flow into the catheter shaft via the injection port. Thus, while acting as a baffle to direct injected fluid toward the proximal occlusion balloon, the elastic sheath also acts as a one-way check valve to prevent unwanted fluid flow back into the injection port.

In this and in other embodiments described herein in which fluid is caused to flow out of a port, the rate of fluid flow out of injection port 208 and into the treatment space between the occlusion balloons may be increased by blocking a lumen in shaft 202, through which the fluid passes, just distal to the port. For example, quick-setting adhesive or silicone may be injected into the lumen just distal to the port so that all fluid flow is directed into the treatment space.

In accordance with any of the embodiments described herein, if photoinitiator is rapidly adherent to the interior lumen tissue wall, then the interior surface may be prestained with photoinitiator before insertion of the device. For example, an artery may be flushed with normal saline, followed by photoinitiator dye in saline. Blood (or other local body fluid) then is allowed to flow while the device is being inserted and located at the treatment site. Although large areas of the vessel wall are stained with photoinitiator according to the method, only at the treatment site defined by the occlusion balloons are both prepolymer and light simultaneously present, thus localizing the creation of a barrier polymer layer.

As noted above, the molding and occlusion elements need not be limited to radially expandable balloons. Rather, occlusion can be achieved using other radially expandable structures. Alternatively, in a lumen having a decreasing diameter in the distal direction, distal occlusion may be achieved by advancing the distal tip of the device until it contacts the lumen walls in a region of decreased diameter.

In the embodiments above, the applied polymer layer has been presented as essentially annular. However, in some circumstances it may be desirable to make a layer which does not entirely cover the inner circumference of the vessel. For example, in any artery, it may be necessary to avoid a major side branch. Non-annular coatings can also be produced by catheters of the invention with minor modifications. For example, the molding balloon, when used, can be eccentric, so that prepolymer is not present on one side of the vessel. Alternatively, light can be prevented from passing through one or more sectors of the balloon or the catheter shaft, thereby preventing crosslinking of polymer in a particular zone. In order to properly position the non-coated zone, the catheter shaft should be provided with means for visualizing its radial orientation within the vessel or lumen. For example, a longitudinal strip of radio-opaque material—optionally also light-opaque—could be mounted on the catheter in the appropriate place.

Equivalents

Although specific features of the invention are included in some embodiments and drawings and not others, it should be noted that certain features may be combined with other features in accordance with the invention.

In addition, it should be noted that the invention is not intended to be limited to the specific materials and construction described herein.

It should be understood that the foregoing description of the invention is intended to be merely illustrative thereof, that the illustrative embodiments are presented by way of example only, and that other modifications, embodiments, and equivalents may be apparent to those skilled in the art without departing from its spirit.

Having thus described the invention, what we desire to claim and secure by Letters Patent is:

1. A method for providing a polymeric coating on a surface of a body lumen which comprises the steps of: